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EXAMINER

VRETTAKOS, PETER J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3739

11

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,811

Applicant(s)

ZVULONI ET AL.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-33 are pending. New art is presented below in response to the claim amendment and arguments posited by the Applicant in Amendment A.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-32 recites the limitation "said table" inline 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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Claims 1-3 and 5-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Holupka et al. ('529).

Independent claim 1

Holupka discloses a planning system for planning a cryosurgical ablation procedure (col. 10:28-33), comprising: a first imaging modality (col. 4: 24-26 and col. 4: 44-47) for creating digitized preparatory images of an intervention site; a three dimensional modeler (14, col. 4:34-40) for creating a three dimensional model of the intervention site based on the digitized preparatory images; and a simulator (13,col. 4:35-40) for simulating a cryosurgical intervention, which comprises an interface useable by an operator for specifying loci for insertion of cryoprobes (19, patented claim 4) and operational parameters (col. 7:56-63) for operation of cryoprobes for cryoablating tissues; and a displayer for displaying in a common virtual space an integrated image comprising a display of the three dimensional model of the intervention site and a virtual display of cryoprobes inserted at the loci (col. 8:7-9). SEE PATENTED CLAIMS.

Dependent Claims

Re: claim 2, Holupka discloses a memory for storing loci for insertion and operational parameters (col. 6:8-10).

Re: claim 3, Holupka discloses a method of computerized tomography, MRI and ultrasound imaging (col. 4: 23-26).

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Re: claim 4: the use of a Cartesian coordinate system to express a 3-D model is a ubiquitous act throughout the scientific modeling community in the majority of fields, including medicine.

Re: claims 5-10, Holupka discloses the ability to highlight selected regions within the 3-D model. Holupka also discloses markers (18, col. 7: 25-33) for the images generated by the MRI or ultrasound devices allowing the modeler to subsequently generate images of the tissue to be cryoablated, as well as the tissue (ex. rectum, bladder) to be protected.

Re: claims 11-15, Holupka implicitly discloses different zones (targeted vs. non-targeted) of relevance to the operation. The demarcation of zones by Holupka is equivalent to disclosing a predictor for predicting probe effects on tissue. Holupka is able to define the specific dimensions of the disclosed zones for each surgery, thereby allowing the operator to better control the destruction of targeted tissue while preserving non-targeted tissue.

Re: claims 4 and 16-22, Holupka discloses an apparatus capable of 3-D modeling used to control the placement and operation of the cryoprobe, thereby indicating that the images provide a *recommended* course of action for the impending surgery. The recommended course of action would inherently (because the following parameters are extant in all cryosurgical procedures) include parameters such as the optimal number of cryoprobes, temperature, duration of cooling, specific locations for insertion, etc.

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Re: claims 23, 27, 28, and 33, Holupka discloses cryosurgical (patented claim 23) prostate (see figure 1a) ablation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24,25, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690).

Holupka neglects to disclose cryosurgical prostate treatment toward BPH.

Mikus et al. discloses, *inter alia*, a cryosurgical prostate treatment toward BPH (col. 1:15-18; col. 2:57). Also disclosed is *percutaneous* prostate cryoablation (col. 3:56).

Therefore, at the time of the invention it would have been obvious to modify Holupka in view of Mikus et al. by including as protocol treatment for the prostate. The motivation would be to provide an additional application for the Holupka ablation system.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Crockett ('488).

Holupka and Mikus neglect to explicitly disclose *transperineal* cryosurgical prostate treatment (col. 3: 65-67).

Crockett discloses *transperineal* cryosurgical prostate treatment.

Therefore, at the time of the invention it would have been obvious to modify Holupka in view of Mikus et al. and further in view of Crockett by including as protocol *transperineal* treatment for the prostate. The motivation would be to provide an additional application for the Holupka ablation system.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Fenn et al. ('426).

Holupka and Mikus neglect to explicitly disclose the use of AUA scores in conjunction with prostate cryoablation.

Fenn et al. discloses the use of AUA scores in conjunction with prostate cryoablation.

Therefore, at the time of the invention it would have been obvious to modify Holupka in view of Mikus et al. and further in view of Fenn et al. by including AUA scores in the protocol. The motivation would be to provide better treatment by using a commonly used indicator of prostate tissue health.

Response to Arguments

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection. New art is presented above.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rubinsky et al. ('810).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

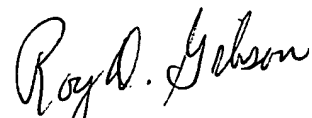
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
July 16, 2003 


ROY D. GIBSON
PRIMARY EXAMINER